FOOD MARKETING INSTITUTE

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November 20, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: PDMA Implementation Regulations, 21 CFR Parts 203, 205; Docket No. 92N-0297

Dear Sir or Madam:

Pursuant to the Food and Drug Administration's (FDA's) September 19, 2000 Federal Register notice, enclosed please find a copy of the testimony presented to the agency on October 27, 2000 by Ty Kelley, Director, Government Relations, on behalf of the Food Marketing Institute (FMI) regarding the agency's rules implementing the Prescription Drug Marketing Act's (PDMA's) "pedigree" requirements. 65 Fed. Reg. 56480 (Sept. 19, 2000).

During the hearing, Mr. Kelley was asked (1) for information on the percentage of pharmaceutical sales in which the product was accompanied by a pedigree and (2) to provide an example of a pedigree currently being used. Mr. Kelley presented the panel's questions to FMI's Pharmacy Committee and to other key pharmacy contacts within our membership. The respondents each indicated that the pharmaceutical products they received were not accompanied by pedigrees as defined by FDA; accordingly, we cannot provide you with a sample pedigree.

We hope you will find Mr. Kelley's testimony useful as you reconsider the agency's PDMA regulations. If we may be of further assistance, please do not hesitate to call on us.

Sincerely,

Deborah R. White

Deborah R. White
Regulatory Counsel

Enclosure

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INTRODUCTION

My name is Ty Kelley, and I am Director of Government Relations for the Food Marketing Institute. FMI is a non-profit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with combined annual sales volume of $300 billion which accounts for more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Additionally, we currently estimate that within our retail membership ranks FMI has about 123 member companies who are in the pharmacy business, operating more than 7,700 in-store pharmacy departments throughout the United States.

FMI appreciates the opportunity to testify at this public hearing, and we commend FDA for delaying the effective date of its final PDMA regulations to allow the agency to receive further information regarding the implications of the rulemaking on the distribution of prescription drugs. Because of the growing prominence of pharmacies in the supermarket industry, and in recognition of the fact that most of our members that operate pharmacies routinely purchase prescription drugs from secondary wholesalers, FMI has a substantial interest in this proceeding. Supermarket pharmacies buy from secondary wholesalers for two key reasons: (1) availability of product when full-line authorized distributors can't deliver what is needed, and (2) lower prices.

FMI'S POSITION ON THE PDMA REGULATIONS

In this regard, our message to FDA is very basic: FMI urges the agency to rescind Section 203.3(u), "Ongoing Relationship," and Section 203.50, "Requirements for Wholesale Distribution of Prescription Drugs," of its PDMA regulations, which were issued in final form on December 3, 1999. While FDA may have issued these two sections of the regulations in an effort to enhance patient safety, FMI has not seen evidence of their health or safety benefits to consumers. In fact, we view these provisions as disruptive to the efficient distribution of prescription drugs and likely to result in higher prices to consumers purchasing needed medications.

Moreover, since PDMA already bans the sale of drug samples, restricts reimportation and prohibits companies from purchasing or selling drug products that came from non-profit hospitals, we strongly believe that Section 203.3(u) and Section 203.50 are simply unnecessary. Additionally, if these sections of the regulations go into effect as is, we understand that they will force some 4,000 small business firms that currently handle prescription drugs to either close down or to drop pharmaceuticals as a product line.

Accordingly, FMI strongly supports a permanent rescission of Section 203.3(u) and Section 203.50 of the final rule or the enactment of legislation that would clarify Congressional intent regarding PDMA as the law relates to wholesale distribution.

RESPONSES TO FDA's QUESTIONS

1. How does the final rule, as published, affect the ability of unauthorized distributors to engage in drug distribution, i.e., what specific requirements would be difficult or impossible for unauthorized distributors to meet? Why?

As FMI understands it, FDA's final rule would require secondary wholesalers to obtain the entire sales history or "pedigree" of each drug all the way back to the manufacturer. In contrast, the agency's regulation does not require a pharmaceutical manufacturer or authorized distributor to provide the "pedigree" to a secondary wholesaler. Thus, without the product's sales history, the secondary wholesaler would not be able to legally sell the product to a retail pharmacy. FMI does not believe that pharmaceutical companies and authorized distributors would be inclined to provide such detailed information, which would include not only all prior sales, but other information such as lot numbers, dosage strength, container size and number of containers simply because this information is not required, would serve no useful purpose and would be burdensome and costly to issue on a regular basis.

2. If the PDMA final rule diminished the ability of unauthorized distributors to engage in drug distribution, what effect would this have on the drug distribution system? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors (authorized and unauthorized) and consumers of drugs?

FMI supermarket members operating in-store pharmacies hold the view that secondary wholesalers play a very important role in the drug distribution system. These small business entrepreneurs not only help to keep prescription drug prices down, but they also fill an important market niche providing legend drugs to low volume customers, such as independent pharmacies, clinics and nursing homes. These are the types of accounts that full-line large drug wholesalers can't profitably serve in the same efficient manner that a secondary wholesaler can. Presently, some 4,000 secondary wholesalers are playing a vital role in helping to distribute prescription drugs nationwide. If these firms are precluded from distributing legend drugs, it is FMI's belief that patient access to life-saving medications will be significantly reduced.

Moreover, all patients can expect to pay more money for prescription drugs if secondary wholesalers are excluded from the distribution system. Some of the key reasons for the vigorous price competition that we see in today's marketplace lie in the prudent purchasing practices of secondary wholesalers. For example, they might forward buy in anticipation of a price increase or purchase large inventories at significant discounts that

are then passed along to retail pharmacies. While FMI cannot predict the exact increase in costs to consumers for prescription medications under this rulemaking, basic economic principles tell us that prices will rise if secondary wholesalers are eliminated from the drug distribution system.

3. If the act were amended by Congress to delete the requirement for provision of a drug pedigree by unauthorized distributors, would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable drugs to consumers and patients?

The Prescription Drug Marketing Act of 1987 establishes significant safeguards to protect consumers from counterfeit, adulterated, misbranded and expired products. Included in these safeguards was the important requirement for State licensing of all wholesale distributors of prescription drugs under Federal guidelines that include minimum standards for storage, handling and recordkeeping.

At issue here is the question of how extensive the recordkeeping must be in order to protect consumers and what Congress intended when PDMA was enacted into law. It is our position that Congress never intended to place so-called "unauthorized distributors" at a competitive disadvantage by imposing a massive recordkeeping burden on the drug distribution system in which a "pedigree" would have to accompany product for each transaction. In fact, the drug distribution system has performed extraordinarily well over the past 12 years since the passage of PDMA without the requirement of "pedigrees" for certain transactions. If there was credible evidence that patients were being harmed because of the lack of "pedigrees," FMI would re-evaluate its position.

FMI wishes to stress that our industry is not seeking to weaken accountability under PDMA or within the drug distribution system. To the contrary, we believe that there is a more reasonable way in which accountability can be achieved rather than by mandating "pedigrees." Such an approach is reflected in legislation (H.R. 4301) that has been introduced by Rep. Jo Ann Emerson (R-MO). This bi-partisan proposal would simply require written certification from an unauthorized distributor that the prescription drugs that are being offered for sale were first purchased from an authorized distributor. In other words, written certification would be similar to a pedigree, but much less costly and burdensome. Moreover, State and Federal officials could easily check written certifications for verification purposes, and firms would be subject to criminal penalties if these documents are found to be falsified.

4. If the act were amended by Congress to require authorized distributors to provide a pedigree, what types of additional costs and burdens would they incur?

While FMI cannot speak for authorized distributors as to the costs and burdens they would incur if a pedigree was required, we would expect the costs to be significant. Regardless of the exact costs associated with a pedigree, they would be passed on to retail pharmacies, which would inevitably mean higher prices to consumers. It makes no sense

to impose such a costly burden on any wholesaler, authorized or unauthorized, without any demonstrated safety benefit for consumers. To the extent that drug wholesalers are already required by FDA to maintain extensive records of all transactions, which are subject to inspection by FDA and by State Boards of Pharmacy, we see a pedigree requirement as unnecessary and duplicative.

5. Could specific changes be made to the information that is required under Section 203.50 to appear on a pedigree to make it more practical, from an authorized distributor's standpoint, to voluntarily provide a pedigree? Would use of a standardized government form be helpful?

As previously mentioned in our response to Question 4, FMI sees no advantage in imposing a pedigree requirement on drug wholesalers. The information that would be provided by the pedigree already exists as part of the distributor's business records that are required by FDA and by state licensing authorities. Furthermore, FMI does not believe that there is any practical way in which distributors could comply with providing a pedigree without incurring significant expenses. If a distributor was required to provide a pedigree, it would mean that the company would have to totally revamp its operations in terms of how product is received, inventoried and transported to its customers to ensure that the pedigree accompanies each and every shipment and transaction.

6. If actual sales by a manufacturer to a distributor were used by FDA as the only criterion to determine whether an ongoing relationship exists between them (and as a result, whether the distributor is an authorized distributor of record), would it result in more distributors being authorized than if a written authorization agreement is required? What other types of criteria might be used by FDA to make this determination?

The "ongoing relationship" criterion is part of FDA's "authorized distributor of record" definition. See 21 U.S.C. § 353(e)(4)(A); 21 C.F.R. § 203.3(b). Actual sales provide a reasonable basis to determine whether a distributor has an "ongoing relationship" and thus qualifies as an "authorized distributor of record" for purposes of the Act. If FDA decided to use actual sales as the sole means by which a determination is made that an ongoing relationship exists between a manufacturer and a distributor, FMI believes that it would result in more distributors being classified as authorized than if the agency required a written authorization agreement.

On the other hand, if FDA were to rely solely on a written agreement under which a distributor is authorized to sell product, there would be far fewer authorized wholesalers. In fact, the trend among pharmaceutical companies in recent years has been to reduce the number of authorized distributors;, a written agreement would likely reduce the ranks of authorized companies at a more rapid pace. As such, drug manufacturers would have greater control over the marketplace in terms of which companies would be authorized to distribute their products. This may mean higher prices for legend drugs to the extent that

pharmaceutical companies would be able to more easily establish exclusive marketing agreements with distributors and dictate pricing schedules for their product lines.

We do not believe that written agreements should be used to determine if a distributor is authorized. Therefore, we believe that FDA's regulation should maintain the agency's original interpretation of the PDMA in which a distributor is deemed "authorized" if the entity has a business relationship with a manufacturer as demonstrated through actual sales. Such guidance regarding an ongoing business relationship was provided by FDA to the regulated industry in August, 1988. At that time, FDA stated that two transactions in any 24-month period would be evidence of a continuing relationship. See Letter from Daniel L. Michels, Director, Office of Compliance to Regulated Industry, Docket No. 88N-258L, August 1, 1988. This guidance from FDA has served the drug distribution system well for more than 12 years, and FMI urges its adoption.

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